

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, et al.,

Plaintiffs,

v.

TRICIDA, INC., et al.,

Defendants.

Case No. 21-cv-00076-HSG

**ORDER REGARDING MOTION TO
CLARIFY**

Re: Dkt. No. 158

Plaintiff moves for an order clarifying the Court’s March 11, 2024 Order Granting in Part and Denying in Part the Motion to Dismiss the Second Amended Complaint (“SAC Order”) (Dkt. No. 145).

Plaintiff contends that the July 29, 2022 Order Granting in Part and Denying in Part the Motion to Dismiss the First Amended Complaint (“FAC Order”) (Dkt. No. 93), “plainly upheld” Defendant Klaerner’s statement expressing confidence in FDA approval on May 7, 2020 as an actionable misrepresentation. Dkt. No. 158 at 1:17. Plaintiff argues that the Court then introduced ambiguity into this “explicit[]” holding in its SAC Order when it included the statement of confidence in a list of non-actionable statements. *Id.* Plaintiff argues that the “explicit[]” holding in the FAC Order should survive because the SAC Order (1) emphasized that it would not revisit the prior rulings and (2) referenced the expression of confidence statement in its scienter analysis. *Id.*

The Court disagrees. First, the FAC Order did not “plainly” or “explicitly” hold that the expression of confidence statement was actionable. In Section III(B)(6)(b) (“Discussing Outstanding Review Issues with the FDA”) of the FAC Order, the Court included a lengthy quote from Klaerner from a May 7, 2020 earnings call:

1 In our late-cycle meeting with [sic] FDA, we took the opportunity to
2 address outstanding review issues. We presented our data and
3 rationale as to why we think we very much satisfied the requirements
4 for initial approval under the Accelerated Approval Program
including the magnitude and durability of the treatment effect on the
surrogate markup serum bicarbonate demonstrated in the TRCA-301
and TRCA-301E trials.

5 Under the initial approval, we have to ensure that US patients
6 who would be prescribed veverimer get clinically significant benefit
7 that outweighs the risk of treatment. Overall, while the FDA continues
its review, we remain confident that our submission meets the
standard for approval through the Accelerated Approval Program.

8 FAC Order at 21–22. The Court held that Plaintiff had plausibly alleged that by disclosing that
9 Tricida discussed “outstanding review issues” with the FDA at the May 1, 2020 meeting and
10 identifying one of those issues (the “magnitude and durability of the treatment effect on the
11 surrogate marker”), Klaerner was also “obligated to share the other significant review issue –
12 ‘applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population.’” *Id.* at
13 22. In other words, the Court held that the relevant statement concerning the “outstanding review
14 issues” addressed in the May 1, 2020 meeting was adequately alleged to be misleading because it
15 omitted a key factor discussed at that meeting. The Court’s analysis of falsity, focusing entirely on
16 the outstanding review issues discussed, did not mention or implicate the statement expressing
17 confidence in approval. *Id.* at 22-23. The Court’s holding here—again, contained in a section
18 titled “Discussing Outstanding Review Issues with the FDA”—was clearly limited to the
19 statement concerning the outstanding review issues discussed with the FDA.

20 The Court’s separate reference to the “we remain confident” statement in its scienter
21 analysis does not disturb the Court’s holding in the FAC Order. *Id.* at 29–30. In the relevant
22 section, notably titled “Statements About Discussing Outstanding Review Issues with the FDA at
23 the May 1, 2020 Late-Cycle Meeting,” the Court analyzed scienter only as to Klaerner’s reference
24 to one rather than both of the review issues discussed at the May 1, 2020 meeting. *Id.*

25 Second, the March 2024 SAC Order resolved any arguable doubt as to the “we remain
26 confident” statement by confirming that the statement was a non-actionable opinion. SAC Order
27 at 12. The Court first noted that “Fiore fails to plausibly allege that Klaerner did not hold the
28 optimistic beliefs he professed, or that these beliefs are objectively untrue.” *Id.* The Court further


1 explained that “the FDA’s expression of its view that the results likely would not be applicable to
2 the U.S. population does not show that Klaerner’s confidence in the likelihood of approval was
3 necessarily false or not honestly held.” *Id.* The Court then concluded that “Klaerner’s failure to
4 disclose all of the specific details of the FDA’s concerns does not render all of his opinions
5 conveying optimism about the approval process false and misleading.” *Id.* at 16. The Court
6 granted Klaerner’s motion as to all challenged opinion statements, including the “we remain
7 confident” statement. *Id.* Although the Court referenced the expression of confidence statement
8 in the scienter analysis, again, this reference does not contradict the Court’s holding that the
9 statement was a non-actionable expression of opinion.

10 Accordingly, the Court re-emphasizes its explicit holding that the “we remain confident”
11 statement is a non-actionable statement of opinion that has been dismissed from this case. *See*
12 SAC Order at 10–16.

13 This Order terminates Dkt No. 158.

14 **IT IS SO ORDERED.**

15 Dated: 7/1/2024

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17 HAYWOOD S. GILLIAM, JR.
18 United States District Judge
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